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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/546,629	10/05/2005	Thomas Buck	8310-5/05.1050.4	8420

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	**PAPER NUMBER**
3768	
MAIL DATE	**DELIVERY MODE**
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Ⲏ

Office Action Summary	Application No.	Applicant(s)	
	10/546,629	BUCK, THOMAS	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 05 October 2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 43-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 43-64 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 23 August 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/23/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed on August 23, 2005 is acknowledged. The information disclosure statements meet the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 43-44 and 46-47, 49-50, 51-54 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. of record ("Flow Quantification in Valvular Heart Disease Based on the Integral of Backscattered Acoustic Power Using Doppler Ultrasound", March 2000) in view of Xi et al. (US Patent No. 6,773,399).

Buck et al. disclose a method for estimating regurgitant flow directly from the Doppler spectrum of the backscattered ultrasound (abstract). To do this, they proposed a method for ultrasound measurement of regurgitant flow at the vena contracta of a regurgitant jet (i.e. an opening surface areas of a dynamic and irregular orifice through which a fluid, such as blood, flows (pg. 309, left column). They apply the Doppler power principle, which comprises evaluating the power spectra of Doppler signals of the

backscattered measurement beams and the reference beam, for noninvasive quantification of regurgitant flow, which includes the step of generating a power profile (pg. 313, left column; pg. 314, Section III.A and Section III.B, pg. 316, Section III.D). They also disclose that the Doppler beam should encompass the entire area of flow (pg. 312, left column, 3rd paragraph). Their method included evaluation of the backscatter of a broad measurement beam having a spatial measurement area and of a narrow reference beam having a spatial measurement area (pg. 314, Section III.A and Section III.B). The calibration of Doppler power measurements is performed using the reference beam (pg. 314, Section III.B). The reference beam serves to establish a ratio between reference power and the known cross-sectional area of the reference beam at the depth (pg. 314, right column, 1st paragraph). The same ratio can be applied to the power measured by the broader measurement beam (pg. 314, right column). A correction factor is used to correct the power from the measurement beam for the decrease in transmit power and receive sensitivity resulting from aperture reduction (pg. 314, Section III.B). As can be seen from Figure 8, the spatial measurement area of the reference beam lies within the spatial measurement area of the measurement beam. The measurement beam and the reference beam are evaluated to obtain absolute values of area, flow rate, and flow volume (pg. 324, left column, 1st paragraph; also see pg. 314-315, Section III.B).

However, Buck et al. do not disclose that at least one of the opening surface area, the volumetric flow rate, the flow volume and any value proportional thereto is determined by the evaluation of several measurement beams with offset spatial,

partially overlapping measurement areas covering the orifice completely and at least one of one reference beam and of several reference beams with offset spatial measurement areas.

Xi et al. discloses an array of ultrasound transducer elements configured to produce ultrasound beams, wherein the beams are generated using subsets of the ultrasound transducer elements which differ by a shift of more than one transducer element (column 4, lines 23-32). Ultrasound beams are produced by subsets of transducer elements, and the generated beams overlap (column 5, line 57 through column 6, line 3). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Buck et al. to determine at least one of the area, flow rate, flow volume by evaluating several measurement beams with offset spatial, partially overlapping measurement areas covering the orifice completely and at least one of one reference beam and of several reference beams with offset spatial measurement areas. The motivation for using several measurement beams with partially overlapping measurement areas and several reference beams would have been to cover a cross-sectional area greater than the width of each individual ultrasound beam, as taught by Xi et al. (column 2, lines 27-35).

Regarding claim 47, Buck et al. disclose applying the Doppler power principle for noninvasive quantification of regurgitant flow, which includes the step of generating a power profile (pg. 313, left column; pg. 314, Section III.A and Section III.B). They also disclose that the Doppler beam should encompass the entire area of flow (pg. 312, left column, 3rd paragraph). However, they do not specifically disclose that the several

measurement beams are evaluated cumulatively, with overlaps of their measurement areas being compensated to generate the power profile which is homogeneous as possible across the entire area. At the time of the invention, it would have been obvious to evaluate the measurement beams cumulatively, with overlaps of their measurement areas being compensated to generate the power profile. The motivation for doing so would have been Doppler Power measurement is calculated using a beam that covers the entire area, as taught by Buck et al., and the measurement beams cover the entire area (pg. 312, left column, 3rd paragraph and pg. 314, Section III.A and Section III.B).

Regarding claim 49, as disclosed by Buck et al. in Figure 8, the measurement area of the reference beam is directed inside of a vena contracta of the fluid flow through the orifice.

Regarding claim 54, Buck et al. disclose that pulsed ultrasound Doppler signals are used (pg. 316, Section III.C).

Regarding claim 57, Buck et al. in view of Xi et al. do not specifically disclose that during a measurement period, at least one of the opening surface area, the volumetric flow rate, the flow volume and the value proportional thereto is determined separately for two or more separate orifices. At the time of the invention, it would have been obvious to have determined one of the parameters discussed above separately for two or more separate orifices. The motivation for doing so would have been that leakage of one or more valves can be caused by various diseases, so the parameters should be determined for more than one valve, as taught by Buck et al. (pg. 307, Section I).

Regarding claim 58, Buck et al. disclose that the results for flow rate can be calculated and displayed, as depicted in Figure 14.

5. Claims 45 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. in view of Xi et al. as applied to claims 43-44 and 46-47, 49-50, 51-54 and 57-58 above, and further in view of Nohara et al. (US Pub No. 2003/0163046).

As discussed above, Buck et al. in view of Xi et al. do not disclose that the central measurement area of a measurement or a central beam is surrounded in a rosette pattern by several measurement areas of further measurement or reference beams. Nohara et al. disclose methods and devices for ultrasonic three-dimensional image acquisition (pg. 1, paragraph [0001]). As depicted in Figure 4, their ultrasonic transducer array is capable of scanning in both the azimuth dimension and in the elevation dimension (pg. 6, paragraph [0070]). From Figure 4, it can be seen that the beams can form a rosette pattern around a central beam (Figure 4). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the central measurement area of a measurement or reference beam be surrounded in a rosette pattern by several measurement areas of further measurement or reference beams. The motivation for doing so would have been to illuminate a volume (i.e. the entire region of interest) as taught by Nohara et al. (pg. 6, paragraph [0070]).

6. Claims 55-56 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. in view of Xi et al. as applied to claims 43-44 and 46-47, 49-50, 51-54 and 57-58 above, and further in view of Nakajima (US Patent No. 4,873,985).

As discussed above, Buck et al. in view of Xi et al. meet the limitations of claim 43. Xi et al. disclose that their method and apparatus can be applied to a two-dimensional transducer array (column 9, lines 3-10). They also disclose that the transmit beams are directed to desired measurement areas (column 4, lines 53-62). However, they do not specifically disclose that the transmit beam is generated by means of a matrix array transducer, nor that several measurement beams and at least one reference beam are detected by means of a matrix array transducer as a function of the measurement areas. Nakajima discloses an ultrasonic imaging apparatus capable of measuring the amount of fluid flowing in an object under examination (column 1, lines 7-10). They disclose the use of a matrix array transducer that transmits and receives ultrasonic beams (column 2, lines 10-48). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Buck et al. in view of Xi et al. to have the transmit beams generated by a matrix array transducer and several measurement beams and at least one reference beam be detected by means of a matrix array transducer as a function of the measurement beams. The motivation for doing so would have been that matrix array transducers can generate multiple beams, as taught by Nakajima (column 1, lines 40-47).

7. Claims 59-60 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. in view of Xi et al. as applied to claims 43-44 and 46-47, 49-50, 51-54 and 57-58 above, and further in view of Buck '181 (US Patent No. 6,544,181).

As discussed above, Buck et al. in view of Xi et al. meet the limitations of claim 43. With regards to claim 62-64, Xi et al. also discloses that their system can be extended to three-dimensional imaging systems (column 9, lines 3-10). However, they do not specifically disclose the limitations of claims 59-60. Buck et al. disclose methods and apparatus for utilizing an ultrasonic pulsed wave Doppler signal to measure the instantaneous area of a dynamic orifice through which blood is passing and/or to measure instantaneous flow rate and flow volume of blood passing through such a dynamic orifice, and identifying the region of flow which is substantially laminar. They disclose that the measurement area of the measurement beam is moved free-dimensionally beforehand in a search mode, while Doppler signals are continuously detected and evaluated in respect of the occurrence of a Doppel spectrum characteristics of a vena contracta, so that thereafter for the determination, the measurement area of the reference beam is directed into the inside of the vena contracta of the fluid flow through the orifice and the measurement area of the measurement beam is directed into the area of the vena contract of the fluid flow through the orifice (column 8, line 49 through column 9, line 21). Further, they disclose that in order to detect a vena contracta, the Doppler signal (Velocity vs. Time) is detected and the bright higher frequency bands from the Doppler signal images correspond to laminar flow (column 8, lines 59 through column 9, line 21). The vena contracta where a laminar flow predominates is located where the narrowness and cleanness of the bright narrow-band spectrum is optimized (column 9, lines 1-21). At the time of the invention, it would have been obvious to include in the invention the

limitations of claim 59 and detect a vena contracta when the Doppler spectrum shows at least a substantially continuous or constant line of maximal speed. The motivation for doing so would have been that the measurement beam should be focused in the area where laminar flow occurs since the Doppler power principle holds only for laminar flow, and at the vena contract it is found that flow is substantially laminar (i.e high velocity) as taught by Buck '181 (column 2, lines 22-43; column 3, lines 5-12).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER